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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,167

03/21/2006

Lars Kilaas

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EXAMINER

DO, PENSEE T

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,167	<b>Applicant(s)</b> KILAAS ET AL.	
	<b>Examiner</b> Pensee T. Do	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 22-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

This application 10519167, filed 03/21/2006 is a national stage entry of PCT/IB03/02994, International Filing Date: 07/01/2003 and claims foreign priority to 0215185.0 , filed 07/01/2002.

### ***Amendment Entry & Claims Status***

The amendment filed on June 23, 2009 has been acknowledged and entered.

Claims 1-55 are pending.

Claims 22-55 are withdrawn from further consideration due to a restriction requirement.

Claims 1-21 are being examined.

### ***Withdrawn Rejection(s)***

Rejection under 112, 2<sup>nd</sup> paragraph in the previous office action is withdrawn.

### ***Maintained Rejection(s)***

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11, 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Weitschies et al. (US 6,027,946).

Weitschies teaches magnetic particle comprising a magnetic material and a matrix/shell comprising functional groups such as aldehyde, thiol. (see col. 7, lines 34-38; col. 5, lines 45-60).

For claims 2-4 and 6, Weitschies teaches the magnetic material comprises ferromagnetic or ferrimagnetic material a magnetic metal oxide such as iron oxides (see col. 7, lines 19-23).

For claim 5, Weitschies teaches the magnetic material is also magnetite. (see example 1).

For claim 7, Weitschies teaches the size of the magnetic particles ranges from 1nm to 1000 nm which is 0.0001 to 100 microns.

For claim 8, Weitschies teaches the particles are spherical by mentioning about the diameter of the particles (see col. 3, line 27).

For claim 9, Weitschies teaches the shell comprises of a polymer. (see col. 7, lines 33-37).

For claim 11, Weitschies teaches using dextran (polymer) coated magnetite particles (see example 1). Dextran is a hydrophilic polymer.

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For claims 13-18, Weitschies teaches the matrix comprises a structure specific substance (refers to the affinant in the present invention), which comprises of a nucleic acid, or antibodies (capable of binding to antigen=protein), biotin, oligonucleotide, DNA, RNA (see col. 5, lines 29-40; col. 9, lines 1-10).

For claim 19, Weitschies teaches that the invention is used in bacteriology, toxicology, infectiology and pathology analysis. (see col. 6, lines 8-11). Bacteriology or pathology detects microbial organism and thus requires a microbial protein or cell to bind to the microbial target organism.

Claims 1 -5, 7-18, 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Tan et al. (US 6,548,264).

Tan teaches a silica-coated nanoparticle. Such nanoparticle comprises a magnetic core and a polymeric shell. (see col. 2, lines 9-15). The polymeric shell is functionalized with a functional group such as carboxylate or amine (see col. 3, lines 35-41).

For claims 2-5, Tan teaches the core comprises of magnetic metal oxide such as iron oxide, i.e. magnetite which is ferrimagnetic (see col. 2, lines 23-30).

For claims 7 and 8, Tan teaches the nanoparticles can be spherical and the diameter ranges from 1-1000 nm (see col. 3, lines 13-16).

For claims 9 and 10, Tan teaches the nanoparticle comprises a polymeric shell, particularly silica-based polymer (see col. 2, lines 9-15; col. 5, lines 53-65).

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For claims 11, 12 and 21, Tan teaches the same functional groups as claimed in the present invention, i.e. carboxylate, amine (see spec. [0031]) which are hydrophilic or hydrophobic. Thus, the functional groups of Tan can also be hydrophilic or hydrophobic. Therefore, the hydrophobic functional groups can be used to bind to hydrophobic target.

For claims 13-19, Tan teaches that the nanoparticles can comprise ligands such as antibody, nucleic acid (oligonucleotide), biotin or streptavidin, or protein (see col. 2, lines 58-65). The nucleic acid bind to a nucleic acid target. The ligand binds to a cell. (see col. 2, lines 66-67).

Claims 1-19, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohr (US 5,445,970).

Rohr teaches magnetic label comprising magnetic core dispersed in a polymeric matrix. (see col. 10, line 1-30, table 1). The magnetic matrix also has functional groups such as aldehydes, carboxylic, epoxide, sulfhydryl, hydroxyl, amino, etc. (see col. 13, lines 42-65).

For claims 2-6, Rohr teaches that the magnetic material comprises of a metal oxide such as iron oxide, and that the magnetic material is ferromagnetic or ferrimagnetic, such as magnetite (see col. 10, lines 1-28).

For claims 7 and 8, Rohr teaches the magnetic particles are spherical and have diameter ranging from 0.01 microns to 1000 microns. (see col. 12, lines 55-65).

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For claims 9, 10, Rohr teaches that the magnetic particles has coating comprising of a polymer or a silica-based polymer (see col. 12, lines 43-54; col. 14, lines 33-55).

For claims 11, 12 and 21, since Rohr teaches using the same functional groups as those claimed by the present invention, i.e. carboxylic, amine, hydroxyl, etc., these functional groups can be hydrophilic or hydrophobic and are usable in non-polar or polar liquid. Rohr also teaches detecting microorganism target. (see col. 5, lines 53-54).

For claims 13-19, Rohr teaches the magnetic particles are derivatized with a binding member for binding to a target, i.e. nucleic acid, or cell such as a microorganism. Such binding member comprises an antibody, avidin, biotin, oligonucleotides. (see col. 5, line 15-col. 16, line 23).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weitschies or Tan or Rohr in view of Nelson et al. (US 5,962,641).

Weitschies, Tan and Rohr have been discussed above but fail to teach the target comprises a metal and the affinant comprises a chelator for the metal.

Nelson teaches that it is well known in the art that several different metal chelating ligands have been employed in immobilized metal ion affinity chromatography (IMAC) to purify proteins. (see col. 1, lines 20-25). Nelson also discloses a novel metal chelating complex for purifying recombinant proteins having a polyhistidine tail or tag. (See col. 4, lines 18-22).

It would have been obvious to one of ordinary skills in the art to use appropriate binder for the analytes being detected, i.e. chelator to detect metal as taught by Nelson, since Weitschies, Tan and Rohr all require a binder/structure specific substance on their nanoparticles to detect analytes.

### ***Response to Arguments***

Applicant's arguments filed June 23, 2009 have been fully considered but they are not persuasive.

Regarding the rejection under 102 (b) by Weitschies et al, Applicants argue that Weitschies only teaches superparamagnetic which is not remanent upon exposure to a magnetic field.

This is not found persuasive because Weitschies teaches that the magnetic particles comprise ferromagnetic or ferrimagnetic material (see col. 7, lines 19-23) which is the same material used in the present invention.



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Regarding the rejection under 102 (e) by Tan et al, Applicants argue that Tan fails to teach a particle having both the required magnetic material and the required matrix material and submit that Tan, in a few variations, discloses particles with cores that can be magnetic (see col. 2, lines 27-29). Applicants also argue that Tan teaches superparamagnetic instead of ferromagnetic material.

Tan teaches a nanoparticle comprises of a core of magnetic material and a matrix of polymeric shell. (see col. 2, lines 9-15). Tan also teaches that the magnetic core is magnetite which is the same material as used in the present invention. Thus, Tan teaches ferromagnetic material.

Regarding the rejection under 102 (b) by Rohr, Applicants argue that Rohr fails to teach magnetic material that is remanent upon exposure to a magnetic field and that Rohr only teaches superparamagnetic material which is not remanent.

Rohr teaches ferromagnetic/ferrimagnetic material such as magnetite (see col. 10, lines 1-28) which is the same material used in the present invention.

Regarding the 103(a) rejection for claim 20, Applicants argue that since Weitschies, Tan and Rohr do not teach magnetic material which is remanent upon exposure of a magnetic field, one of ordinary skills in the art would not combine these references with Nelson. Applicants also submit that the office has provided no technically sound, apparent reason why a person skilled in the art would have had any reasonable expectation of success in combining these references.

First of all the reason for combining Weitschies, Tan or Rohr with Nelson has been established in the previous office action and restated in the rejection discussed above.

Since Weitschies, Tan and Rohr have been discussed above to teach that the magnetic particles are ferromagnetic or magnetite which is the same material used in the present invention, the magnetic particles in these references should function the same way as those in the claimed invention. Furthermore, Weitschies, Tan and Rohr also teach the same matrix material which is made up of functional groups or polymers as those claimed in the present invention, such matrix would be able to promote disaggregation of the particles in the presence of a liquid phase.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/  
Examiner, Art Unit 1641

/Mark L. Shibuya/  
Supervisory Patent Examiner, Art Unit 1641